UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,503	06/07/2001	Hiroshi Oda	11283-009001	1563

7590 12/05/2001

Fish & Richardson
Suite 2800
45 Rockefeller Plaza
New York, NY 10111

EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	6

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/786,503	Applicant(s) ODA ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgement is made to amendment filed on June 7, 2001. Claims 1-12 are pending.

Specification

1. The disclosure is objected to because of the following informalities:

Page 11, line 13 "indicat or" should be --indicator--.

Page 17, line 7 "analys is" should be --analysis--.

Appropriate correction is required.

Claim Objections

Claims 5, 6 and 9-12 are objected to because of the following informalities:

Claim 5 line 2 "hypertensiton" should be --hypertension--.

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 is a duplicate claim of claim 5.

Claims 9-12 "any one of claims 8" should be --claim 8--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2 and 4-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining the concentration of lipocalin-type prostaglandin D synthase (L-PDGS) in a body fluid sample taken from a subject and comparing it to a reference value, which may led to detection of an early renal disease such as claimed, does not reasonably provide enablement for detection of a specific renal disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. The factors that must be considered in determining undue experimentation are set forth in *In re W*ands USPTQ2d 14000. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The disclosure fails to state or teach one skilled in the art how to specifically use the L-PGDS concentration to detect a specific renal disease. The specification on pages 18 and 19 disclose the correlation of L-PGDS to a renal disease and that L-PGDS is superior to serum creatinine and urinary albumin in diagnosing a renal disease. However, it is not disclosed in the specification of the ability of L-PGDS to

detect a specific renal disease such as glomerulonephritis, nephritic syndrome, diabetic nephropathy, polycystic kidney or hypertension associated kidney diseases.

The specification on pages 19 and 20 disclose changes in L-PGDS concentrations in diabetic patients and that L-PGDS can be an indicator of progression of diabetic nephropathy superior to serum creatinine and urinary albumin. However, it is not disclosed in the specification of the ability of L-PGDS to specifically detect diabetic nephropathy.

The specification lacks a clear written disclosure of how the detection of L-PGDS in a body fluid may be related to a specific renal disease. At best, the detection of an increased level of the detection of L-PGDS as compared to normal healthy subjects, indicate renal disease and not a specific renal disease. Such is not seen as sufficient to support the breath of the claims and without this disclosure, one skilled in the art cannot practice disease state management without undue experimentation because in order to manage the disease, one skilled in the art would have to know what the disease is.

The prior art (Hoffman, Molecular characterization of Beta-trace protein in human serum and urine: a potential diagnostic marker for renal diseases, Glycobiology, Vol. 7, no. 4, p 504, col 2, lines 61-63) teaches that alterations in concentration or amount of beta-trace protein (L-PGDS) have also been discussed to be implicated in a variety of other diseases such as cerebral infarction, multiple sclerosis, and schizophrenia.

4. Hoffman et al indicates that an increased level of L-PGDS may be related to several conditions. Thus, because the state of the art is highly unpredictable and without specific guidance in the specification as to how the specific renal disease may be inferred from the increased L-PGDS, one skilled in the art cannot make and use the invention as claimed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite. The recitation "disease state management" it is unclear how the disease state is managed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al (Molecular characterization of Beta-trace protein in human serum and urine: a potential diagnostic marker for renal diseases, Glycobiology, Vol 7, no. 4, p 499-506 (1997).

Hoffman et al disclose that beta-trace protein (lipocalin-type prostaglandin D synthase (L-PGDS)) was isolated from cerebrospinal fluid, serum, plasma and urine samples of normal volunteers and sera and hemofiltrate of patients with chronic renal failure (abstract). Hoffman et al disclose that serum L-PGDS concentration in patients with end-stage renal failure increased as compared to the L-PGDS of the normal volunteers. Hoffman et al disclose that serum beta-trace (L-PGDS) concentrations were determined by quantitative immunoaffinity chromatography in conjunction with amino acid sequencing and SDS gel electrophoresis and revealed a broad range of concentrations (p. 504, col 2, lines 36-60). Hoffman et al also disclose that since L-PGDS accumulates more significantly in serum in pathological conditions than other proteins, the L-PGDS may be used for the study and early diagnosis of renal diseases (p. 505, lines 14-21).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Atkinson et al (US Patent 5,762,937) disclose that early detection provides an opportunity for treatments which can forestall or prevent the serious health problems associated with the clinical stage of IDD (col 3, lines37-49).

Conklin et al (US Patent 6020163) disclose lipocalins are small secreted proteins that are believed to be involved in the transport of small, hydrophobic molecules (col 1 lines 10-16).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
December 3, 2001

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
12/03/01